

# 3

Animal Product  
Manual

## Reference

### *Miscellaneous Products*

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#### Introduction

The *Miscellaneous Products* section covers products which **do not** fit appropriately under any other section in the *Reference* chapter. These products are listed as follows:

- ◆ Asian medicinal products
- ◆ Birds' nests
- ◆ Cosmetics
- ◆ Fomites
- ◆ Human pharmaceuticals that contain animal-derived components<sup>1</sup>
- ◆ Human vaccines that contain animal-derived components<sup>1</sup>

<sup>1</sup> If there are no animal-derived components, then the product is unrestricted.

- ◆ Products of biotechnology
  - ❖ DNA
  - ❖ Plasmid
  - ❖ Probe
  - ❖ RNA
- ◆ Salt scrapings

These products are regulated because they are at risk of transmitting animal disease viruses. The products can transmit viruses by association with animals or by being made from animal by-products.


Also, listed in the locator ([Table 3-15-2](#)) are examples of miscellaneous products that are admissible and **do not** require a VS permit.

When a VS permit authorizes entry of the miscellaneous product, match the following information on the shipping documents with that on the permit:

- ◆ Current date
- ◆ Description of the material
- ◆ Shipper
- ◆ Consignee
- ◆ Conditions spelled out on the permit

Follow [Table 3-15-1](#) as you match the permit with the shipping documents.

**TABLE 3-15-1 Action to Take on Miscellaneous Products Imported Under VS Permit**

If:	And the shipping documents:	And the:	Then:
Miscellaneous products imported under VS Permit	Match the permit		RELEASE or CONTROL as specified on the permit
	<b>Do not</b> match the permit	Permit has expired	1. <b>DO NOT</b> RELEASE the HOLD 2. HAVE the consignee contact VS, TTSPS for renewal (see <a href="#">page 2-4-27</a> ) 3. SAFEGUARD the importation until you hear from VS, TTSPS
		Discrepancy is <b>other than</b> an expired permit	1. <b>DO NOT</b> RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <a href="#">Appendix H</a> )

## Locator

When a VS permit does **not** authorize entry, use **Table 3-15-2** which directs you to the final regulatory action to take.

**TABLE 3-15-2 Determine Where to Find the Regulatory Action on Miscellaneous Products Not Authorized by a Permit**



If:	And the importation is:	Then:
Miscellaneous products that are <b>not</b> authorized by a permit	Animal products to be incorporated into cosmetics	GO to <a href="#">Table 3-15-12</a>
	Antibiotics	RELEASE
	Asian medicinal products	GO to <a href="#">Table 3-15-13</a>
	Birds' nests	GO to <a href="#">Table 3-15-3</a>
	Cheese and yogurt starters ◆ <i>Lactobacillus</i> sp. ◆ <i>Streptococcus</i> sp. ◆ Fungi, including yeast	RELEASE
	Chemically synthesized, biosynthesized, and natural products	GO to <a href="#">Chemically Synthesized, Biosynthesized, and Natural Products</a> on <a href="#">page 3-15-19</a>
	Fomites (carriers, footwear, garbage, used farm machinery, meat covers, semen and embryo containers, hay or straw, egg cartons, crates, flats, or liners)	GO to <a href="#">Fomites</a> on <a href="#">page 3-15-5</a>
	Fungal cultures (non-pathogenic to livestock or avian)	RELEASE <b>only</b> if <b>not</b> a plant pest
	Human pharmaceuticals, including dietary supplements, and human vaccines	Go to <a href="#">Human Pharmaceuticals and Human Vaccines</a>
	Paraffin or resin embedded materials (non-livestock)	RELEASE

## Birds' Nests

Birds' nests are imported for both edible and inedible purposes. Edible birds' nests are the dried, glutinous secretion from salivary glands of Southern Asiatic swifts. These nests are used in making soup.

Apply plant regulations to all importations of birds' nests. They **must** be free from soil and prohibited plant material such as wheat (or related genera) straw, rice straw, corn (or related genera) straw, noxious weed propagules, or parasitic plants and their seeds.

TABLE 3-15-3 Birds' Nests

If the birds' nests are:	And the country of origin is known to be:	And the importation:	Then:
<ul style="list-style-type: none"> <li>◆ Edible</li> <li>◆ Inedible</li> </ul>	Affected with HPAI (H5N1) <b>only</b>	Is accompanied by a VS permit	RELEASE   <b>Important</b> <div style="background-color: #e0f2f1; padding: 5px; margin-top: 5px;">The importation may be subject to plant regulations.</div>
		Lacks a VS permit	REFUSE ENTRY
	Affected with <b>both</b> HPAI (H5N1) and END	Is accompanied by a VS permit	RELEASE   <b>Important</b> <div style="background-color: #e0f2f1; padding: 5px; margin-top: 5px;">The importation may be subject to plant regulations.</div>
		Lacks a VS permit	REFUSE ENTRY
	Affected with END <b>only</b>	Is appropriately certified <sup>1</sup>	RELEASE
		Lacks certification	REFUSE ENTRY
	Free from both HPAI (H5N1) and END	→	RELEASE

<sup>1</sup> An official government veterinary certificate stating the birds' nests were heated to a minimum internal temperature of 161°F (72°C).

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## Fomites

Fomites are inanimate objects that may be contaminated with animal disease viruses and could transmit those viruses into the United States. Fomites are those importations which are likely to have come in contact with animals or animal products, such as:

- ◆ Barn dirt
- ◆ Barn sand
- ◆ Barns (brick, adobe, wood)
- ◆ Carriers
- ◆ Clothing
- ◆ Containers
- ◆ Egg cartons, crates, flats, or liners
- ◆ Farm machinery, used
- ◆ Feed
- ◆ Feeders
- ◆ Feed utensils
- ◆ Footwear
- ◆ Garbage
- ◆ Garden soil
- ◆ Hair, livestock
- ◆ Hay
- ◆ Meat covers
- ◆ Pails
- ◆ Road sand
- ◆ Semen and embryo containers
- ◆ Soil
- ◆ Stalls
- ◆ Straw, hay, and grass
- ◆ Vehicles
- ◆ Walls, brick, and plaster
- ◆ Wood

Procedures for taking regulatory action on some of the fomites listed above occur in the *Manual for Agricultural Clearance (MAC)*, and are also regulated under the plant regulations and appear in the *Plant Import—Nonpropagative Volume of Manuals*.

### Carriers Including Containers

Aircraft, ship, railroad car, and truck carriers and containers are considered a risk when found contaminated with evidence of blood, hay, straw, manure, or garbage. Procedures for taking action on trucks from Mexico that are found contaminated with animal material are covered under ***Trucks Transporting Livestock from Mexico*** on **page 2-2-12**. Procedures for taking action on other contaminated carriers are in *Manual for Agricultural Clearance (MAC)* and will **not** be repeated here.

### Egg Cartons, Crates, Flats, or Liners

Egg cartons, crates, flats, or liners can be contaminated with blood, feathers, manure, shell, or egg. Go to **Table 3-15-4** for action to take.

TABLE 3-15-4 Egg Cartons, Crates, Flats, or Liners

If:	And upon inspection, the packing material is:	Then:
◆ Eggs cartons	Clean and uncontaminated	RELEASE
◆ Egg crates		
◆ Egg flats	Contaminated with blood, egg shell, egg breakage, feathers, or manure	REQUIRE the importer to REMOVE and DESTROY the packing material
◆ Egg liners		

## Used Farm Machinery

Used farm machinery includes vehicles, equipment, and other implements used in agricultural and farming operations. Go to [Table 3-15-5](#) to regulate imported farm machinery that is used (**not** new).

TABLE 3-15-5 Imported, Used Farm Machinery

If:	And the country or region of origin is known to be:	And the importation:	And visual inspection reveals the machinery:	Then:
Imported, used farm machinery	Affected with FMD	Is appropriately certified <sup>1</sup>	Is clean	RELEASE
			Is <b>dirty</b> <sup>2</sup>	1. COMPLETE PPQ Form 523, Emergency Action Notification 2. PROVIDE the importer with the appropriate options ❖ RE-EXPORT ❖ CLEAN and WASH <sup>3</sup>
		Lacks the appropriate certification	→	1. REFUSE ENTRY 2. PROVIDE the importer with the appropriate options (see <a href="#">Table 2-2-11</a> )
	Free from FMD	→	Is clean	RELEASE
			Is <b>dirty</b> <sup>2</sup>	1. COMPLETE PPQ Form 523, Emergency Action Notification (since dirty farm machinery is unrestricted from FMD-free countries, this is to take care of plant pests) 2. REQUIRE that the equipment be cleaned and washed prior to entry

1 A government certificate signed by an official representative of the national health service of the region or area of origin [for example, UK Department of Environment, Food and Rural Affairs (DEFRA)]. The certificate **must** carry an official seal and a statement declaring that, "The used farm equipment indicated on this certificate has been steam cleaned and is free of all dirt and particulate matter." In addition, the certificate **must** also supply the following information:

- ◆ Date of issue of the certificate
- ◆ Name and address of the applicant
- ◆ Name and address of the consignor
- ◆ Name and address of the consignee
- ◆ Date the equipment was cleaned
- ◆ Container number or marks
- ◆ Serial number of each piece of equipment
- ◆ Name of vessel or carrier
- ◆ Bill of lading number
- ◆ Description of the piece of equipment

The Vietnamese regulatory agency for issuing and certifying certificates of steam cleaning for used farm equipment is "The Vietnam Pesticide Company/Termite Control & Fumigation Company."

2 If a coating of road film is the **only** visible dirt found, and **no** other organic matter is present, RELEASE the machinery.

- 3 Used farm machinery that is dirty may be allowed entry if the machinery is cleaned at a port which has a cleaning facility. If the port of entry **does not** have a cleaning facility, then the importer or the importer's agent may choose to send the machinery directly to a port with a cleaning facility. However, **never** allow overland transport. If the cleaning option is **not** selected, the importer or the importer's agent **must** re-export the machinery within 48 hours. If workable, take digital photographs of the equipment and the certificate and submit to the PPQ Veterinary Medical Office (e-mail <Margaret.M.Dziedziak@usda.gov>) for follow-up with the country or region that supplied the certification.

### Footwear

Shoes or boots which have been used on a farm or ranch that has livestock or poultry and is located in a country with diseases of concern, may be contaminated. Procedures for taking action on footwear are under **Articles That Require Cleaning and Disinfection** on page 2-4-13.

### Garbage

Garbage includes all waste material derived from fruit, vegetables, meat, or other plant or animal (including poultry) parts; any refuse associated with the waste material on board a carrier, including food scraps, table refuse, galley refuse, food wrappers, or packaging material; other waste material from stores, food preparation areas, passengers' or crews' quarters, dining rooms, or any other area on a carrier. Garbage also means food and meals that were available for consumption by passengers and crew on a carrier, but were **not** consumed. Procedures for controlling garbage are in the *Manual for Agricultural Clearance* (MAC) and will **not** be repeated here.

### Semen and Embryo Containers

All containers that have been previously used to transport semen or embryos present a risk of introducing animal diseases. These containers may be manifested as nitrogen containers. First, you **must** ensure that the semen or embryo containers are empty. Then you can take the appropriate action based on the country of origin and animal class of the semen or embryo. The procedures for handling empty semen or embryo containers are under the *Procedures* section, **Clearing Regulated Cargo**.



## Straw, Hay, and Grass, and Canadian Origin Soil

Straw, hay, and grass can be contaminated by animal diseases through association with animals. Such plant material may also harbor ticks. Therefore, straw, hay, and grass imported as animal feed, as animal bedding, as packing material, or for manufacturing is regulated under animal regulations.

The following straw, hay, or grass materials are **not** subject to animal regulations:

- ◆ Manufactured items such as mats, hats, souvenirs, jackets, brooms, and naturally dried flowers
- ◆ Straw, hay, or grass obviously selected, processed, and packed for sale or distribution as decorative material
- ◆ Related plant products such as broomcorn, sugarcane, corn, silage soybeans, soybean meal, and flax

Note that these previously bulleted importations may be subject to plant regulations and appear in the *Plant Import: Nonpropagative Volume of Manuals*.




Importations of Canadian origin soil are **unrestricted** due to animal health concerns. Importations of straw, hay and grass from Canada, New Zealand, and Norway are **unrestricted** since these countries are free from fever ticks and FMD; however, importations from all countries may be subject to plant regulations.

TABLE 3-15-6 Straw, Hay and Grass

If:	And the country of origin is:	And:	And:	Then:
<ul style="list-style-type: none"> <li>◆ Grass</li> <li>◆ Hay</li> <li>◆ Straw</li> </ul>	Canada or New Zealand	_____→		RELEASE
	Mexico	The State of Chihuahua, or Sonora, or the Mexicale region of Baja California Norte	Certified <sup>1</sup>	1. <b>DO NOT RELEASE</b> the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <a href="#">Appendix H</a> )
			Lacks certification <sup>1</sup>	
	Other than Canada, Mexico, or New Zealand	_____→	_____→	GO to <a href="#">Table 3-15-7</a>

<sup>1</sup> Certified by a salaried, federal veterinarian of the Mexican government as originating from the State of Chihuahua or Sonora or the Mexicale region of Baja California Norte.

**TABLE 3-15-7 Straw, Hay and Grass from Countries Other Than Canada, Mexico, New Zealand, or Norway**

If:	And the country of origin is:	And is the importation is to be used for:	And the importation is:	Then:
<ul style="list-style-type: none"> <li>◆ Grass</li> <li>◆ Hay</li> <li>◆ Straw</li> </ul>	Other than Canada, Mexico, New Zealand, or Norway	Animal feed or bedding		<ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <a href="#">Appendix H</a>)</li> </ol>
		Manufacturing	Consigned to an approved establishment for disinfection	AUTHORIZE shipment under seal with a VS Form 16-78 (see <a href="#">Appendix K</a> to complete the form)
			<b>Not</b> consigned to an approved establishment for disinfection	<ol style="list-style-type: none"> <li>1. REFUSE ENTRY</li> <li>2. PROVIDE the importer with the appropriate options (see <a href="#">Table 2-2-11</a>)</li> </ol>
		Packing material		<ol style="list-style-type: none"> <li>1. ALLOW importer to remove if practicable; otherwise REFUSE ENTRY</li> <li>2. REQUIRE that the packing material be destroyed</li> <li>3. GO to <a href="#">Disinfection</a> on <b>page 2-4-13</b></li> </ol>
		Samples for research		<ol style="list-style-type: none"> <li>1. ADVISE importer that a VS permit is required to authorize entry</li> <li>2. PROVIDE importer with the appropriate options (see <a href="#">Table 2-4-16</a> on <b>page 2-4-27</b>)</li> </ol>

## Used Meat Covers and Scrap Bagging

Meat covers are burlap or cloth covers that were previously used to wrap fresh or frozen meat. Also regulated are mixed importations of scrap bagging with one or more pieces of material identified as being used to cover meat.



Important

Used burlap bags and covers which have been used for plant products are regulated under the plant regulations. Refer to the *Plant Import: Nonpropagative Volume of Manuals*.

**TABLE 3-15-8 Used Meat Covers and Scrap Bagging**

If the importation is:	And the country of origin is known to be:	Then:
<ul style="list-style-type: none"> <li>◆ Used meat covers</li> <li>◆ Scrap bagging</li> </ul>	Free from ASF, CSF, SVD, and FMD	RELEASE
	Affected with ASF, CSF, SVD, or FMD	1. REFUSE ENTRY 2. PROVIDE the importer with the appropriate options (see <a href="#">Table 2-2-11</a> )

## Human Pharmaceuticals and Human Vaccines

To regulate imported pharmaceuticals, first read the label or accompanying data sheet, fact sheet, or information sheet. The label and sheets are your main source for information about the product's ingredients. The label should identify any animal-derived components that are present in the product. Continue to [Table 3-15-9](#).



Read the label first (and any accompanying data, fact, or information sheets) to ascertain if the product contains any animal-derived components.

TABLE 3-15-9 Regulatory to Take on Human Pharmaceuticals and Human Vaccines

If:	And after reading the label, you verify that there are:	Then:
◆ Human pharmaceuticals	No animal-derived components in the product	RELEASE
◆ Human vaccines	Animal-derived components in the product	GO to <a href="#">Table 3-15-10</a>


**TABLE 3-15-10 Human Pharmaceuticals and Human Vaccines Containing Animal-Derived Components**

If:	And is:	And the product is:	And is:	And the importation:	Then:
◆ Human pharmaceuticals containing animal-derived components  ◆ Human vaccines containing animal-derived components	Antivenom	_____	_____	➔	1. <b>DO NOT RELEASE</b> the HOLD 2. ADVISE the importer of the HOLD because the importation requires a VS permit authorizing its entry 3. PROVIDE the importer with the appropriate options, including applying for a veterinary import product permit issued by VS, TTSPS (see <a href="#">page 2-4-27</a> )
	Dietary supplement	_____	_____	➔	
	Insulin	_____	_____	➔	
	Nutriceutical (including chondroitin sulfate and glucosamine)	Other than marine derived	_____	➔	
		Wholly marine derived	◆ Fish oil ◆ Fish meal ◆ Rendered marine product <b>other than</b> chondroitin sulfate and glucosamine	➔	
			◆ Chondroitin sulfate ◆ Glucosamine	Is accompanied by a shipper's or producer's declaration <sup>1</sup>	<b>DO NOT RELEASE</b> the HOLD until the importer provides the required statement
				Lacks the appropriate declaration <sup>1</sup>	1. <b>DO NOT RELEASE</b> the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <a href="#">Appendix H</a> )
	Human pharmaceutical	_____	_____	➔	GO to <a href="#">Table 3-15-11</a>
	Human vaccine	_____	_____	➔	

<sup>1</sup> An **original** written declaration and signed statements on the producer's or shipper's letterhead which states and affirms in a clear and concise manner, the following information:

- ◆ Identification of the material and species of origin
- ◆ The material **does not** include any avian, equine, ruminant, or swine species or their materials (such as media or stabilizers)

**TABLE 3-15-11 Human Pharmaceuticals and Human Vaccines Containing Animal-derived Components Other than Antivenom, Dietary Supplement, Insulin, or Nutraceutical (Including Chondroitin Sulfate and Glucosamine)**

If the importation is:	And is:	And the product:	And the importation:	Then:
Human pharmaceuticals or human vaccines containing animal-derived components	<b>Other than</b> antivenom, dietary supplement, insulin, or nutraceutical (including chondroitin sulfate and glucosamine)	Is in final dosage form	Is accompanied by the shipper's or producer's declaration <sup>1</sup>	RELEASE
			<b>Lacks</b> the shipper's or producer's declaration <sup>1</sup>	<b>DO NOT</b> RELEASE the HOLD until the importer provides the required statement
		Is <b>not</b> in final dosage form		<ol style="list-style-type: none"> <li><b>DO NOT</b> RELEASE the HOLD</li> <li>ADVISE the importer of the HOLD because the importation requires a VS permit authorizing the entry of the importation</li> <li>PROVIDE the importer with the appropriate options including applying for a veterinary import product permit issued by VS, TTSPS (see <a href="#">page 2-4-27</a>)</li> </ol>


1 An **original** written declaration and signed statements on the producer's or shipper's letterhead that states and affirms in a clear and concise manner, the following information:

- ◆ Detailed, accurate description of the material
- ◆ The product has "is intended for human use **only**" written on the label; the product **does not** contain any livestock or poultry viral agents; and the product is prepared, packaged, and physically labeled in final-dosage form and ready for sale to the consumer

## Cosmetics

Cosmetics may have several ingredients of animal origin; however, if those cosmetics are packaged and ready for sale, then they are unrestricted. **Only** bulk components of animal products **other than** tallow derivatives to be incorporated into cosmetics are regulated.

TABLE 3-15-12 Cosmetics Containing Animal Products

If:	And the cosmetics are:	And the importation:	Then:
Cosmetics containing animal products	Shipped In final, finished packaging and ready for sale		RELEASE
	Shipped as bulk components of animal origin <sup>1</sup> to be incorporated into cosmetics	Is accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
		<b>Lacks</b> a VS permit	REFUSE ENTRY
	Shipped as bulk components of animal origin <sup>1</sup> to be repackaged into final, finish form and ready for sale	Accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
		<b>Lacks</b> a VS permit	REFUSE ENTRY

<sup>1</sup> Components of animal origin except for tallow derivatives. For example, amniotic fluid extract, amniotic liquid, collagen, extracts of connective tissue, or placental extract.

## Asian Medicinal Products



Asian medicinal products are regulated to exclude animal diseases. Importations may include, but are **not** limited to the following animal by-products:

- ◆ Antlers
- ◆ Bones
- ◆ Extracts
- ◆ Glands
- ◆ Hoofs
- ◆ Organs
- ◆ Secretions
- ◆ Skin
- ◆ Tendons
- ◆ Tissue

Examine the by-products to determine their origin. If you **cannot** determine the origin, then look at an invoice or label, and ask the importer.

To locate the regulatory action to take on Asian medicinal products, continue to [Table 3-15-13](#).

TABLE 3-15-13 Asian Medicinal Products

If:	And the products' origin is:	And the source is:	Then:
Asian medicinal products	Animal	◆ Equine ◆ Ruminant ◆ Swine	GO to <a href="#">Table 3-15-14</a>
		◆ Bird ◆ Poultry	GO to <a href="#">Table 3-15-15</a>
		<b>Other than</b> listed above	RELEASE
	Plant		REFER to the <i>Plant Import: Nonpropagative Volume of Manuals</i>
	Mineral		RELEASE



## Asian Medicinal Products of Equine, Ruminant, or Swine Origin

TABLE 3-15-14 Asian Medicinal Products of Equine, Ruminant, and Swine Origin

If the Asian medicinal product's source is:	And the country of origin is known to be:	And the product is:	And is:	And:	Then:
Ruminant	Affected with BSE	—————→		—————→	REFUSE ENTRY
	Free from BSE	Processed	—————→	Is accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
			—————→	<b>Lacks</b> a VS permit	REFUSE ENTRY
		Fresh (chilled or frozen)	<ul style="list-style-type: none"> <li>◆ Extracts</li> <li>◆ Glands</li> <li>◆ Organs</li> <li>◆ Secretions</li> </ul>	Consigned to an approved establishment	AUTHORIZE shipment under seal with VS Form 16-78 (see <a href="#">Appendix K</a> to complete)
				<b>Not</b> consigned to an approved establishment	1. <b>DO NOT</b> RELEASE the HOLD 2. HAVE the importer consign the shipment to an approved establishment; if <b>no</b> approved establishment exists, then have the importer apply for a VS permit (see <a href="#">page 2-4-27</a> )
			<ul style="list-style-type: none"> <li>◆ Tendons</li> <li>◆ <b>Other than</b> extracts, glands, organs, or secretions</li> </ul>	Is accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
				<b>Lacks</b> a VS permit	REFUSE ENTRY
<ul style="list-style-type: none"> <li>◆ Equine</li> <li>◆ Swine</li> </ul>	—————→	Processed	—————→	Is accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
			—————→	<b>Lacks</b> a VS permit	REFUSE ENTRY
		Fresh (chilled or frozen)	<ul style="list-style-type: none"> <li>◆ Extracts</li> <li>◆ Glands</li> <li>◆ Organs</li> <li>◆ Secretions</li> </ul>	Consigned to an approved establishment	AUTHORIZE shipment under seal with VS Form 16-78 (see <a href="#">Appendix K</a> to complete)
				<b>Not</b> consigned to an approved establishment	1. <b>DO NOT</b> RELEASE the HOLD 2. HAVE the importer consign the shipment to an approved establishment; if <b>no</b> approved establishment exists, then have the importer OBTAIN a VS permit
			<ul style="list-style-type: none"> <li>◆ Tendons</li> <li>◆ <b>Other than</b> extracts, glands, organs, or secretions</li> </ul>	Is accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
				<b>Lacks</b> a VS permit	REFUSE ENTRY

## Asian Medicinal Products of Bird or Poultry Origin

**TABLE 3-15-15 Asian Medicinal Products of Bird or Poultry Origin**

If the Asian medicinal product's source is:	And the country of origin is known to be:	And the product is:	And is:	And:	Then:
<ul style="list-style-type: none"> <li>◆ Bird</li> <li>◆ Poultry</li> </ul>	Affected with HPAI (H5N1) <b>only</b>	Processed	→	Is accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
			→	<b>Lacks</b> a VS permit	REFUSE ENTRY
		Fresh (chilled or frozen)	→	→	REFUSE ENTRY
	Free from HPAI (H5N1)	Processed	→	Is accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
			→	<b>Lacks</b> a VS permit	1. REFUSE ENTRY 2. PROVIDE the importer with the appropriate options (see <a href="#">Table 2-2-11</a> )
		Fresh (chilled or frozen)	<ul style="list-style-type: none"> <li>◆ Extracts</li> <li>◆ Glands</li> <li>◆ Organs</li> <li>◆ Secretions</li> </ul>	Consigned to an approved establishment	AUTHORIZE shipment under seal with VS Form 16-78 (see <a href="#">Appendix K</a> to complete)
				<b>Not</b> consigned to an approved establishment	1. DO NOT RELEASE the HOLD 2. HAVE the importer consign the shipment to an approved establishment; if <b>no</b> approved establishment exists, then have the importer apply for a VS permit (see <a href="#">page 2-4-27</a> )
			◆ Tendons	Is accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
				<b>Lacks</b> a VS permit	REFUSE ENTRY
			Other than extracts, glands, organs, secretions, or tendons	Is accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
				<b>Lacks</b> a VS permit	REFUSE ENTRY

## Chemically Synthesized, Biosynthesized, and Natural Products

### Introduction

The chemically synthesized, biosynthesized, and natural products section covers chemically synthesized products and products having to do with or formed from biotechnology. These recombinant products result from foreign genes being inserted into microorganisms (for example, yeast and bacteria) or cells (i.e., cell culture). Genetic materials (DNA or RNA for example) can be produced either through biotechnology or chemical synthesis.

A list of some chemically synthesized and biosynthesized (recombinant), and natural products and their categories follows in [Figure 3-15-1](#).

Biosynthesized Proteins	Chemically Synthesized Products	Genetic Materials
<ul style="list-style-type: none"> <li>◆ Amino acids</li> <li>◆ Enzymes</li> <li>◆ Growth factors</li> <li>◆ Hormones</li> <li>◆ Interleukins</li> </ul>	<ul style="list-style-type: none"> <li>◆ Chemicals</li> <li>◆ Lipopeptides</li> <li>◆ Oligopeptides</li> <li>◆ Polypeptides</li> <li>◆ Steroids</li> </ul>	<ul style="list-style-type: none"> <li>◆ cDNA probes</li> <li>◆ DNA vector</li> <li>◆ Nucleic acids (DNA, RNA)</li> <li>◆ Plasmids (DNA, cDNA)</li> <li>◆ Primers (nucleotides)</li> </ul>



**FIGURE 3-15-1** List of Chemically Synthesized, Biosynthesized, and Natural Products and Their Categories

In regulating these products, you need to determine whether the product was chemically synthesized (i.e., synthetic) or biosynthesized (recombinant). If the product was biosynthesized, you need to further determine whether the product was produced in cell culture or microbially.

Use the [Glossary](#) and [Index](#) to determine if a product fits under this section of synthetic or biosynthesized products. Determine whether a product is synthetic by using accompanying statements from producers and shippers.


When a VS permit does **not** authorize entry to the material, use [Table 3-15-16](#) which directs you to the final regulatory action to take.

**TABLE 3-15-16 Locator for Chemically Synthesized, Biosynthesized, and Natural Products**

If:	And the product is:	And is:	Then:
<ul style="list-style-type: none"> <li>◆ Biosynthesized products</li> <li>◆ Chemically synthesized products</li> <li>◆ Natural products</li> </ul>	<ul style="list-style-type: none"> <li>◆ Nucleic acid (RNA, DNA)</li> <li>◆ Plasmid</li> <li>◆ Primer</li> <li>◆ Probe</li> </ul>		GO to <a href="#">Table 3-15-20</a>
		Livestock or avian	CONTACT <a href="#">PPQ-AQI-VMO</a> or <a href="#">PPQ-VRS-Headquarters Personnel</a> for further action (see <a href="#">Appendix H</a> )
		Derived from infectious livestock or avian microorganisms (bacteria, viruses)	CONTACT <a href="#">PPQ-AQI-VMO</a> or <a href="#">PPQ-VRS-Headquarters Personnel</a> for further action (see <a href="#">Appendix H</a> )
		Unrelated to any livestock (ruminant, equine, or swine) or avian (bird) species	GO to <a href="#">Table 3-15-18</a>
		Recombinant, microbial, or synthetic	GO to <a href="#">Table 3-15-18</a>
	Not a tissue, protein, peptide, or plasmid		CONTACT <a href="#">PPQ-AQI-VMO</a> or <a href="#">PPQ-VRS-Headquarters Personnel</a> for further action (see <a href="#">Appendix H</a> )

## Proteins/Peptides/Enzymes/Hormones

**TABLE 3-15-17 Proteins/Peptides/Enzymes/Hormones**

If:	And:	And the origin is:	Then:
<ul style="list-style-type: none"> <li>◆ Enzymes</li> <li>◆ Hormones</li> <li>◆ Peptides</li> <li>◆ Proteins</li> </ul>	Unrelated to any livestock (ruminant, equine, or swine) or unrelated to any avian (bird species)	Recombinant, microbial	GO to <a href="#">Table 3-15-18</a>
		Chemically synthesized materials (amino acids, hormones, steroids)	GO to <a href="#">Table 3-15-19</a>
		Amphibian, aquatic species, or reptile	GO to <a href="#">Table 3-8-11</a>
		Feline (cat) or canine (dog)	GO to <a href="#">Table 3-8-10</a>
		Laboratory animal (includes gerbils, guinea pigs, hamsters, mice, rabbits, and rats)	GO to <a href="#">Table 3-8-7</a>
		Nonhuman primate	GO to <a href="#">Table 3-8-9</a>
		Cell culture	CONTACT <a href="#">PPQ-AQI-VMO</a> or <a href="#">PPQ-VRS-Headquarters Personnel</a> for further action (see <a href="#">Appendix H</a> )
	Related to livestock or avian species		CONTACT <a href="#">PPQ-AQI-VMO</a> or <a href="#">PPQ-VRS-Headquarters Personnel</a> for further action (see <a href="#">Appendix H</a> )

## Proteins/Peptides/Enzymes/Hormones of Microbial Origin Including Recombinants

TABLE 3-15-18 Proteins/Peptides/Enzymes/Hormones of Microbial Origin Including Recombinants

If:	And the origin is:	And the importation:	Then:
<ul style="list-style-type: none"> <li>◆ Enzymes</li> <li>◆ Hormones</li> <li>◆ Peptides</li> <li>◆ Proteins</li> </ul>	Microbial, including recombinants	Is accompanied by a shipper's or producer's declaration <sup>1</sup>	RELEASE
		<b>Lacks</b> the shipper or producer's declaration <sup>1</sup>	CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <a href="#">Appendix H</a> )

1 An **original** written declaration and signed statements on the producer's or shipper's letterhead which states and affirms in a clear and concise manner, the following information:

- ◆ Detailed description of the material including the genetic insert if applicable
- ◆ Indicates the material is microbially produced

## Chemically Synthesized Proteins, Peptides, Enzymes, Hormones

TABLE 3-15-19 Chemically Synthesized Proteins/Peptides/Enzymes/Hormones




If:	And the importation is:	Then:
<ul style="list-style-type: none"> <li>◆ Chemically synthesized enzymes</li> <li>◆ Chemically synthesized hormones</li> <li>◆ Chemically synthesized peptides</li> <li>◆ Chemically synthesized proteins</li> </ul>	Is accompanied by a shipper's or producer's declaration <sup>1</sup>	RELEASE
	<b>Lacks</b> the shipper or producer's declaration <sup>1</sup>	<b>DO NOT RELEASE</b> the HOLD until importer provides required documentation

1 An **original** written declaration and signed statements on the producer's or shipper's letterhead which states and affirms in a clear and concise manner, the following information:

- ◆ Provides a description of the material
- ◆ Indicates that the material is chemically synthesized

## Plasmids, Nucleic Acids (RNA, DNA), Primers, Probes

TABLE 3-15-20 Plasmids, Nucleic Acids, Primers, Probes

If:	And:	And the importation:	Then:
<ul style="list-style-type: none"> <li>◆ Nucleic acids (RNA, DNA)</li> <li>◆ Plasmids</li> </ul>	Do not contain genetically or non-genetically engineered infectious plant pests (virus genome, bacteria, fungi)	Is accompanied by a shipper's or producer's declaration <sup>1</sup>	RELEASE
		Lacks the shipper or producer's declaration <sup>1</sup>	DO NOT RELEASE the HOLD until the importer provides the required documentation
	Contain genetically or non-genetically engineered infectious plant pests (virus genome, bacteria, fungi)		CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <a href="#">Appendix H</a> )
<ul style="list-style-type: none"> <li>◆ Primers</li> <li>◆ Probes</li> </ul>		Is accompanied by a shipper's or producer's declaration <sup>1</sup>	RELEASE
		Lacks the shipper or producer's declaration <sup>1</sup>	DO NOT RELEASE the HOLD until importer provides required documentation


1 An **original** written declaration and signed statements on the producer's or shipper's letterhead which states and affirms in a clear and concise manner, the following information:

- ◆ Description of the material
- ◆ Indicates the material is produced synthetically or through biotechnology

## Salt Scrapings

Salt scrapings is salt that has been reclaimed from salted casings. The product is usually imported as a brine solution discolored with a red dye. The discoloration is used so the scrapings **do not** enter the human food chain.

TABLE 3-15-21 Salt Scrapings from Animal Casings

If:	And the salt scrapings are from a country of origin that is:	And the importation:	Then:
Salt scrapings from animal casings	Affected with ASF or BSE		1. <b>DO NOT</b> RELEASE the HOLD 2. PROVIDE the importer with the appropriate options (see <a href="#">Table 2-2-11</a> )
	Free from ASF and BSE	Is accompanied by a veterinary certificate <sup>1</sup>	RELEASE
		Lacks the certification <sup>1</sup>	<b>DO NOT</b> RELEASE the HOLD until the importer provides the required certification

<sup>1</sup> A veterinary certificate endorsed by the veterinary service of the country from which the salt (brine) from animal casings was reclaimed. The certificate **must** identify the following:

- ◆ The species of animal the casings were from
- ◆ The country or region where the animal casings were processed

